

**REMARKS/ARGUMENTS**

The Final Office Action of April 16, 2008 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1-11, 13-21, 23, 28-29, 32, 37-38, and 43-48 are pending. Claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 were rejected under 35 U.S.C. §102(b)/§103(a) as being anticipated/rendered unpatentable by U.S. Patent No. 6,128,538 to Fischell *et al.* (Fischell). Claims 47-48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell in view of U.S. Patent No. 6,690,974 to Archer *et al.* (Archer). In response, Applicants respectfully traverse the rejection in view of the following remarks.

**Rejection under 35 U.S.C. §102(b)/§ 103(a) – Fischell**

Claims 11-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 stand rejected under 35 U.S.C. § 102(b)/ § 103(a) as being anticipated/rendered unpatentable by Fischell. Claims 1, 14, 28, 29, 32, 37, 38, 43 and 45 are independent.

As an initial matter, the prior ground of rejection has not been maintained. Therefore, and contrary to the Examiner's suggestion, it appears that the prior arguments made by Applicants were deemed persuasive and therefore the prior ground for rejecting the claims has been withdrawn.

Turning to the current rejection, independent claim 1 recites the features "preventing the therapy device from delivering therapy to the patient for a predetermined quantity of block counts after the therapy device has been activated, wherein the predetermined quantity of block counts is configured to allow the seizure detection algorithm to stabilize." It was previously admitted that Fischell does not disclose preventing therapy for a predetermined quantity of block counts after the therapy device is activated:

10. Fischell discloses the claimed invention except for the preventing of therapy for a predetermined quantity of block counts after the therapy is activated. Chen discloses

Office Action of September 13, 2007, page 3. In spite of this prior admission, the Office Action now suggests that Fischell anticipates claim 1. Given the prior admission and the statement that Fischell does not explicitly disclose starting the detection device, the suggestion that Fischell anticipates claim 1 is not persuasive. Notably, Fischell makes no mention of stabilizing a

detection algorithm – indeed the terms stable or stabilize are not found in Fischell. Instead Fischell merely points out that the detection algorithm can be set so it will not immediately react to a single sensed signal but instead will wait until there are a sufficient number of sensed signals so as to avoid providing a false positive. This falls short of disclosing the recited stabilizing of the detection algorithm. Furthermore, there is nothing in Fischell (or anything else of record) to suggest that the detection algorithm of Fischell requires or would benefit from a stabilizing period. Thus it is relatively clear that Fischell does not disclose, inherently or otherwise, the above recited feature of claim 1.

The Office Action goes on to say that in the alternative, it would have been obvious to have the algorithm stabilize as it is allegedly well known to do so. On the one hand, Applicants read this as an admission that Fischell does not actually disclose the above recited feature of claim 1. On the other hand, this suggestion is completely conclusory because no support has been provided to show why it would be obvious to include a stabilizing period in the detection algorithm of Fischell. Furthermore, no support has been provided for the suggestion that it is well known to stabilize event detection algorithms. Therefore, the Office Action has not satisfied the requirement of providing a logical rationale to support the rejection. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) (“To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).”). Importantly, there has been no support provided that shows the detection algorithm of Fischell could be stabilized, or that it would benefit from stabilizing. Thus, any suggestion that it would be obvious to include the above recited feature of claim 1 necessarily lacks support.

In addition, claim 1 recites “preventing the therapy device from delivering therapy to the patient for a predetermined quantity of block counts after the therapy device has been activated...” (emphasis added). Fischell discloses requiring a predetermined number of signals and therefore attempting to wait a predetermined time period would prevent Fischell from working as intended. Consequentially, a person of skill in the art would not find it obvious to

modify the disclosure of Fischell to reach the claimed subject matter. Thus, the proposed rationale for modifying Fischell is not supported. Accordingly, Fischell does not support a *prima facie* case of obviousness with respect to claim 1 and claim 1 is patentably distinct in view of Fischell.

Independent claims 14, 43 and 45 recite features similar to the features discussed above with respect to claim 1 and, therefore, are patentably distinct over Fischell for at least the reasons that claim 1 is patentably distinct. In addition, claims 43 and 45 recite a feature similar to the feature “preventing the therapy device from delivering therapy to the patient for a predetermined time period immediately after the therapy device has been activated” recited in claim 43 (emphasis added). The Office Action has provided no support for this feature being disclosed by Fischell or that it was obvious to modify Fischell to include this feature and the argument that claim 1 does not include this feature does not address the fact that claims 43 and 45 do recite this feature.

Claims 2-11, 13, 15-20, 23, 44 and 46 depend from one of the independent claims 1, 14, 43 and 45 and, therefore, are patentably distinct for at least the reasons that the independent claims 1, 14, 43 and 45 are patentably distinct and for the additional features recited therein.

Independent claims 28, 29, 32, 37 and 38 recite features similar to the features “determining whether the programming information can result in delivery of therapy with a number of stimulations per detection being above a predetermined limit of stimulations per detection” and “preventing the therapy device from being configured according to the programming information if it could result in delivery of a number of stimulations per detection above the predetermined limit of stimulations per detection” as recited in claim 28. The Office Action addressed this feature with respect to claim 32 only (and thus has not provided a proper rejection of claims 28, 29, 37 and 38), and suggested error handling was known, thus it would have been obvious to modify Fischell to include error handling.

As an initial matter, no support was provided for this statement, thus the required rationale has not been provided. In addition, this general and unsupported statement does not address the above recited features but at most addresses a more general case not present here. Notably, it is axiomatic that a genus does not necessarily anticipate a species. Therefore, the

Office Action has provided no support for the features recited in claims 28, 29, 32, 37 and 38 as being present in or obvious modifications of Fischell. In other words, the rejection is too conclusory to be considered supported by a proper rationale. Thus, for at least this reason claims 28, 29, 32, 37 and 38 are patentable over Fischell.

In addition to failing to provide support for the above similar features, claim 32 further recites the feature “determining whether the programming information can result in stimulation ON time being outside of an acceptable range of between 1 second and 24 hours.” As admitted, Fischell does not disclose this feature. In this regard, as previously noted, the reasoning of *In re Aller*, 105 USPQ 233, that once the general conditions are disclosed in the prior art, discovering the optimum or workable range is not patentable has no application here. This is because the Office Action cannot point to the disclosure of a workable range and instead is arguing that it would be obvious to modify Fischell to include error handling in the first place. Thus, the Office Action admits that the workable range was not disclosed in the prior art. To put it another way, if the Office Action is suggesting that features from different references can be combined to show the features of a claim, it cannot also suggest that one of those references discloses a workable range so as to apply *In re Aller*. Therefore, unlike *In re Aller*, this is not a case of simply finding the optimum range from a disclosed workable range but instead is more of a case of finding the workable range.

Claim 32 further recites the features of “calculating parameters that will be used to control a stimulation ON time” and “providing programming information based on the calculated parameters for configuring the therapy device to deliver therapeutic treatment to the body via the therapy delivery element.” The Office Action has failed to provide any support for the suggestion that Fischell discloses, teaches, or suggests the feature “calculating parameters that will be used to control a stimulation ON time.” Indeed, the disclosure in Fischell regarding stimulation is relatively terse – the vast majority of Fischell is directed to signal processing and little is said about stimulation. Applicants have been unable to find any mention of such a calculating. Furthermore, as Fischell does not contemplate the idea of “calculating parameters that will be used to control a stimulation ON time” Fischell necessarily cannot disclose, teach, or suggest “providing programming information based on the calculated parameters for configuring

the therapy device to deliver therapeutic treatment to the body via the therapy delivery element.” The rejection has simply failed to address these features in a sufficient manner and therefore has failed to make a *prima facie* case of obviousness with respect to claim 32 for this additional reason.

Accordingly, for at least the above reasons withdrawal of this ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a) – Fischell & Archer**

Claims 47 and 48 depend from claim 29, which as noted above, is neither anticipated nor rendered obvious by Fischell. Archer was not suggested to correct the above noted deficiency in Fischell, thus the combination of Fischell and Archer fail to support a *prima facie* case of obviousness. Accordingly, for at least the reasons discussed above with respect to claim 29, claims 47 and 48 are patentable.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

**CONCLUSION**

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

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